REMARKS

I. Status of the Claims

With entry of the amendments herein, claims 13, 15-22, 37, 39-46, 49, and 51 - 61 are pending in this application; claims 1-12, 23-36, 47, and 48 were previously cancelled. Independent claims 13, 37, and 49 are amended herein to incorporate the phrase "wherein the weight ratio of EPA:DHA in the fatty acid composition is 1:X, where X is equal or greater than 1." Support for those amendments can be found throughout the specification and in now cancelled claims 14, 38, and 50. Applicants added new claims 53-61. Support for those claims can be found at, *e.g.*, [0066] and [0071] - [0082] of the published application. Accordingly, no new matter is added by the amendments herein.

Applicants thank and acknowledge the Examiner's withdrawal of the rejection under 35 U.S.C. § 102(b) over U.S. Patent No. 5,502,077 to Breivik et al. ("Breivik"). Office Action at page 2.

II. Rejection Under 35 U.S.C. § 103

The Office maintains the rejection of claims 13-22, 37-46, and 49-52 under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No. 5,502,077 to Breivik et al. ("Breivik") in view of U.S. Patent Application Publication No. 2005/0019372 to Corkey et al. ("Corkey"). Office Action at page 5. Applicants continue to respectfully disagree and traverse this rejection for the reasons of record and the following reasons below.

In response to Applicants' arguments filed on June 9, 2009, the Office now asserts that Corkey "is sufficient for what it shows." *Id.* at page 2. Specifically, the Office highlights that Corkey demonstrates an expectation of success with standard amounts of EPA and DHA. *Id.* at pages 2, 3. Further, the Office relies on Corkey to show that "an individual administered these specific components in preferred and/or standard formulations would reasonably achieve the same claimed results of applicants' invention." *Id.* at page 3. The Office further alleges that Corkey links cardiovascular disease with obesity, and Breivik discloses the limitation of "DHA rich" by the ratio of 1:1. *Id.* The Office's response to Applicants' arguments, as in the prior Office Action, fail to appreciate the teachings of the references themselves, as a whole.

Prior art references, in this case the cited art references of Breivik and Corkey, must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. M.P.E.P. § 2141.02(VI). When Breivik and Corkey are considered "as a whole," gaping holes are found not only in their teachings, but also in their combination to arrive at the presently claimed invention.

For example, as previously articulated, Breivik, *inter alia*, does not even suggest treatment of obesity and/or an overweight condition as recited in the present claims. Instead, Breivik broadly teaches that "[t]he compositions [of Breivik] can be used for the treatment or prophylaxis of *multiple risk factors* for cardiovascular diseases." Breivik at Abstract (emphasis added). However, the "risk factors" of cardiovascular disease articulated in Breivik include "hypertension, hypertriglyceridemia and high coagulation factor VII phospholipid complex activity"; nothing is said regarding obesity or even

suggested.[1] *Id.* at Col. 10, ll. 34-39. According to the M.P.E.P., "[t]he discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using." M.P.E.P. §2112.02 (citations omitted). Applicants submit that the present disclosure comprises a new and unobvious use of DHA and EPA.

The Office attempts to remedy Breivik's deficiencies by including the teachings of Corkey. However, Corkey teaches in a different direction.

Corkey teaches dietary products comprising a combination of milkfat-derived medium-chain triglycerides (MCT) and long-chain triglycerides (LCT), and "a small portion" of omega-3 fatty acids. Corkey at [0006], [0121]. Corkey discloses that "[t]he present inventors have discovered that MCFA [medium chain fatty acids] can regulate both triglyceride storage and differentiation of fat cells." *Id.* at [0025]. Corkey's disclosure is premised on an understanding of "the mechanisms by which MCFA regulate metabolism of fat cells . . . to formulate dietary supplements and products aimed at reducing fat mass during development." *Id.* at [0026]. Results are presented "show[ing] that MCFA can have a significant impact on fat cell development and metabolism in vitro." *Id.* at [0102]. Corkey discloses adding small amounts of EPA and DHA only to "synergize" with the effects of MCFA. *Id.* at [0121]. The skilled artisan would thus reasonably understand that MCFA are an essential component in the disclosed compositions that provide for regulation of body metabolism. As a result, any

[1] Breivik also provides for "[o]ther possible medical indications" that include "chronic polyarthritis, psoriatic artheritis, periarteritis nodosa, lupus erythematosus disseminatus (LED), sclerodermia, Crohn's disease, ulcerative colitis, psoriasis, atopic dermatitis and migraine." *Id.* at col. 11, ll. 1-7. Again, none include treatment of obesity or an overweight condition.

alleged reasonable expectation of success stems from the *combination* of MCFA and EPA/DHA in Corkey not from any of the individual ingredients alone.

This also holds true for Corkey's alleged teaching that links obesity with cardiovascular disease. *See* Office Action at page 2; *see also*, Corkey at [0006]. Corkey's disclosure of "preventing obesity" and "reducing serum TGs (in particular, serum TGs associated with traditional MCT diets)" is within the context again of a specific *combination* of MCFAs *and* EPA/DHA. Corkey at [0006]. As such, Corkey provides no teaching or suggestion of the individual components as a means to control obesity alone.

Even if one were to take Corkey's teaching of the combination and modify to use only the specific ingredients, which Applicants do not concede, proceeding contrary to this teaching is evidence of nonobviousness. M.P.E.P. § 2143(X)(3) (citing *In re Hedges*, 783 F.2d 1038, 228 U.S.P.Q. 685 (Fed. Cir. 1986)). For at least those reasons, the Office's arguments that Corkey provides a standard amount of EPA and DHA and link between cardiovascular disease and obesity are within the context of the *combination* of MCFA *and* EPA/DHA disclosed in Corkey.

The Office further asserts that with respect to the ratio range, which is now recited in amended independent claims 13, 37, and 49, "[t[here is no suggestion in the current claim set that 'DHA rich' would not reasonably extend to a ratio as disclosed of 1:1 as supported by Breivik et al." Office Action at page 3. As previously highlighted, Breivik teaches that "[t]he upgrading of the EPA fraction to obtain a weight ratio of EPA:DHA of from 1:1 to 2:1, especially 3:2 or the upgrading of the DHA fraction to obtain a EPA:DHA weight ratio of from 1:1 to 1:2 may be achieved in the molecular

distillation stage." Breivik at Col. 3, ll. 61-65. However, Breivik specifically states that "an *especially preferred* composition according to the present application comprises . . . a ratio of EPA:DHA from 1:1 to 2:1, *especially* about 3:2." *Id.* at Col. 3, ll. 4-10 (emphases added). The example pharmaceutical preparation at Col. 11 of Breivik further shows EPA ethyl ester at 525 mg/capsule and DHA ethyl ester at 315 mg/capsule (i.e., a higher EPA value). Taking Breivik's disclosure as a whole, Breivik directs one to a higher level of EPA not DHA and thus, in a different direction than that recited in the present claims. Corkey is silent on EPA:DHA ratios, and thus cannot cure the deficiencies of Breivik.

For at least the reasons above, neither Breivik, nor Corkey, alone or in combination, provide a basis for establishing a *prima facie* case of obviousness over the present claims. Accordingly, Applicants request that the rejection be withdrawn.

III. Conclusion

Applicants submit that the rejections are overcome by the foregoing amendments and arguments and request the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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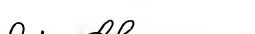
Dated: December 22, 2009

By: 
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